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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/350,518 | 07/09/1999 | JOHN C. REED | P-LJ-3578 | 8259 |

41552 7590 02/15/2005

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| EXAMINER |
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HOLLERAN, ANNE L

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Anne Holleran

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-66.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2/14/2005.
10. ☐ Other: _____

Alana M. Harris
ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
02/14/2005

Continuation of 5. does NOT place the application in condition for allowance because: arguments and the Turner et al reference (exhibit) were not persuasive to overcome the grounds of rejection. The claims are rejected under 35 USC 112, 1st paragraph because, as explained in the final rejection, the full scope of the claims is not enabled by teachings of the specification. The teachings in the specification concerning the use of BAG-1 protein levels for the prognostication of breast cancer are exemplified by a working example that demonstrates the use of H-scores to dichotomize a data set. The full scope of the claims reads on methods using "reference levels" of BAG-1, which would be used in the claimed inventions to distinguish a group of breast cancer patients having a "high" level of BAG-1 expression. The examples referred to in the reply of reference levels that may be determined by measuring BAG-1 levels in cultured cells or in normal breast cells are prophetic, and it is unclear that one of skill in the art would be able to determine what would be appropriate reference levels using cultured cells or normal breast cells, given the guidance presented in the specification. The Turner reference, which was not included with the reply, but was considered and has been listed on an 892, is not persuasive in overcoming the instant rejection of the claims, because Turner appears to be a restatement of the data already presented in the specification, and is directed to the use of H-scores for dichotomization of data, and not to methods for determining "reference levels" .